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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/813,319	03/21/2001	Ming-Hui Wei	CL001066-CIP	1556

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EXAMINER
BERTOGLIO, VALARIE E

ART UNIT	PAPER NUMBER
1632	

DATE MAILED: 06/23/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/813,319	WEI ET AL.	
	Examiner	Art Unit	
	Valarie Bertoglio	1632	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *25 August 2004*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *4,8,9 and 24-30* is/are pending in the application.

4a) Of the above claim(s) *24* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *4,8,9 and 25-30* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *08/04*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

Applicant's reply filed 08/25/2004 has been received. Claims 1-3,5-7 and 10-23 are cancelled. Claim 24 has been withdrawn. Claims 4,8,9 and 24-30 are pending and claims 4,8,9 and 25-30 are under consideration in the instant office action.

Election/Restrictions

Claim 24 was withdrawn in the office action dated 03/24/2004 as being drawn to a non-elected invention on the grounds that it is drawn to a method of using a cell to make a polypeptide that is not necessary for and is patentably distinct from the elected invention. Applicant traverses this restriction requirement as claims to a polynucleotide, vectors, and host cells comprising the polynucleotide have always been joined with the method of producing the polypeptide.

In response, this argument is not persuasive because the elected invention is related to the method of claim 24 as a product (the cells) and process of using wherein the product can be used in other methods and, as well, the protein can be made using other methods. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product (MPEP § 806.05(h)). In the instant case the cells can be used to determine the effects of overexpressing the gene encoded by SEQ ID NO:1, or simply to propagate the nucleic acid for use as a probe.

The examiner has required restriction between product and process claims. Where applicant elects claims directed to the product, and a product claim is subsequently found

allowable, withdrawn process claims that depend from or otherwise include all the limitations of the allowable product claim will be rejoined in accordance with the provisions of MPEP § 821.04. **Process claims that depend from or otherwise include all the limitations of the patentable product** will be entered as a matter of right if the amendment is presented prior to final rejection or allowance, whichever is earlier. Amendments submitted after final rejection are governed by 37 CFR 1.116; amendments submitted after allowance are governed by 37 CFR 1.312.

In the event of rejoinder, the requirement for restriction between the product claims and the rejoined process claims will be withdrawn, and the rejoined process claims will be fully examined for patentability in accordance with 37 CFR 1.104. Thus, to be allowable, the rejoined claims must meet all criteria for patentability including the requirements of 35 U.S.C. 101, 102, 103, and 112. Until an elected product claim is found allowable, an otherwise proper restriction requirement between product claims and process claims may be maintained. Withdrawn process claims that are not commensurate in scope with an allowed product claim will not be rejoined. See "Guidance on Treatment of Product and Process Claims in light of *In re Ochiai, In re Brouwer* and 35 U.S.C. § 103(b)," 1184 O.G. 86 (March 26, 1996). Additionally, in order to retain the right to rejoinder in accordance with the above policy, Applicant is advised that the process claims should be amended during prosecution either to maintain dependency on the product claims or to otherwise include the limitations of the product claims. **Failure to do so may result in a loss of the right to rejoinder.**

Therefore, the restriction requirement is deemed proper and is made FINAL.

Priority

Applicant has updated the priority information in the first line of the specification.

Drawings

The drawings are objected to because the figures are not labeled in compliance with 37 CFR 1.84(u)(1), which requires that figures with the multiple views be labeled with the same numeral followed by successive letters, e.g. Figure 1A, 1B, 1C. Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Objections

Claim 4 remains objected to for reasons of record set forth on page 3 of the office action mailed 03/23/2005. Applicant has failed to address the objection.

Claim Rejections - 35 USC § 101/112-1st paragraph

35 U.S.C. 101 reads as follows:

> Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claims 4,8,9 and 25-30 remain rejected under 35 U.S.C. 101 because the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility as set forth on pages 3-7 of the office action mailed 03/24/2005.

Applicants' arguments have been fully considered and are not found persuasive.

The claimed invention is directed to a nucleotide sequence that encodes a novel human phosphatase. The instant specification has contemplated that the nucleotide sequence set forth in SEQ ID NO: 1 encodes a human phosphatase based on its homology with other human phosphatases (page 6, lines 20-25). The specification has provided numerous general assertions and speculative uses for the claimed nucleic acids and cells comprising the claimed nucleic acids including use as probes, primers, chemical intermediates and use in biological assays (page 34, lines 9-10).

However, the specification fails to provide a specific and substantial utility for the claimed nucleotide sequences or the polypeptide that they encode. Applicant's specification fails to provide a "real world" use of the nucleic acids set forth in SEQ ID NO:1 or 3 or of any nucleic acid that encodes the polypeptide set forth in SEQ ID NO: 2. Neither the specification as filed, nor any art of record disclose or suggest any biological or biochemical activity for the protein encoded by SEQ ID NO: 1 or 3 or any nucleic acid encoding the polypeptide set forth by SEQ

ID NO:2, such that any utility would be well established for the protein. The asserted utilities for the claimed nucleic acids such as a probe for diagnosing a disease, primers for PCR, or chemical intermediates is merely a "potential" use that applies to any uncharacterized, unrelated polynucleotide sequences. Therefore the asserted utilities are not considered "specific" utilities, i.e. they are not specific to SEQ ID NO:1,2 or 3.

It is unclear, based on the teachings of the specification, exactly which type of phosphatase is encoded by the claimed sequence, or what substrates the putative phosphatase acts on and what type of cellular process it affects. The PPM1G subfamily of phosphatases has no demonstrated link to any disease. The general class of phosphatases is comprised of many members, which have different chemical structures, different tissue specificities, different activators and inhibitors, and more importantly, different substrates. The specification (see pages 1-4) and the state of the art teaches the variability in function of known phosphatases as regulators of processes as diverse as cell growth, differentiation, cell-to cell contacts, cell cycle progression and oncogenesis (see Li, 2000 and Ceulmans, 2004 and page 6 of the office action mailed 03/24/2004). These references demonstrate the biochemical diversity between phosphatase family members and their differing roles in various cell processes. Neither the specification nor any art of record has taught the activity of the phosphatase set forth by SEQ ID NO:2 leaving the skilled artisan to speculate and investigate the uses of the uncharacterized phosphatase.

Applicants argue that the claimed molecules have uses within the commercial marketplace in drug development since they encode unidentified members of pharmaceutical targets (see Applicants' remarks at page 4, paragraph 3).

In response, evidence of commercial success of the claimed nucleic acids is not of record and there are no teachings on the record regarding what the commercial use may be so as to determine whether those uses are patentable under the utility guidelines (see REVISED INTERIM UTILITY GUIDELINES TRAINING MATERIALS; repeated from http://www.uspto.gov/web/menu/utility.pdf).

Applicant argues that demonstration of specific therapeutic use is not required. Applicant cites *Nelson v. Bowler*, 206 USPQ 881 (CCPA 1980). Applicant recites :

> The CCPA held that where a claim does not provide evidence of pharmacological activity of a claimed compound, although it does not establish a specific therapeutic use, manifests a practical utility because knowledge of pharmacological activity is beneficial to the public in that it makes faster and easier for medical researchers to combat illnesses. Nelson v. Bowler, 206 USPQ 881 (CCPA 1980).

Applicant argues that even entry points to the drug discovery cycle are useful based on the *Nelson* case. Applicant argues that the isolated nucleic acid encoding a phosphatase has useful value in the drug discovery process even though it may not be associated with a specific treatment of a particular disease. Applicant states that *Nelson* allows for the assertion that the present invention provides sufficient knowledge and information that is beneficial to the public and to researchers.

In response, Applicant has failed demonstrate that the instant specification provides any such sufficient knowledge and information that is beneficial to the public and to researchers. The specification fails to demonstrate any activity or role for the claimed nucleic acid. The claimed nucleic acid merely has homology to other phosphatases that have roles in a variety of tissue and a variety of unrelated processes. Applicants' assertions amount merely to a wish to know. With respect to Nelson, the CCPA held that the board was improper in that while a specific therapeutic use had not been established, pharmacological activity had been. The CCPA deemed that the

evidence of pharmacological activity of the claimed compounds as disclosure of the pharmaceutical activity of compounds is useful to researchers. This does not correlate to the case at hand wherein the activity of the claimed nucleic acid has not been demonstrated. The claimed nucleic acid is homologous to a huge family of phosphatases with diverse activities, specificities and in vivo roles. Providing this nucleic acid and cells cannot be correlated to the scenario presented by *Nelson* wherein the in vivo activity of a compound is used to support its utility.

Applicants argue that the utility rejection conflicts with *Juicy Whip v. Orange Bang* (Fed. Cir. 1999) that held that to violate to utility requirement an invention must be totally incapable of achieving a useful result. Applicant holds that the nucleic acids of the instant invention are well known in the art to be useful drug targets and have readily apparent commercial utilities.

In response, again, the specification fails to demonstrate a function for the claimed nucleic acid. It is not known, without knowing the activity of the claimed nucleic acid, what its role could potentially be. There is no support for the claimed nucleic acid being a useful drug target.

Applicant argues that the Li reference cited by the Examiner does not apply as it pertains to the diversity of a different phosphatase family (page 5, last paragraph). While it is agreed that the teachings of Li are with specific regards to PTPs, it is maintained that the same level of diversity exists for serine/threonine phosphatases (see Ceulemans, 2004).

Applicants argue that the specification discloses that PPM1G has specific function in pre-mRNA spicing and spliceasome assembly (page 6, 1st paragraph). In response, the instant invention involves a splicing variant of PPM1G that lacks 3 entire exons. The activity of this splice variant is not demonstrated.

Applicant argues that numerous phosphatases have been useful developing therapeutics (page 6, paragraphs 2-3). Applicant asserts that placing a new member of the phosphatase protein family into the public domain makes a clear advancement over the prior art and will shorten the process for researchers to discover other novel uses for the instant invention.

In response, the utility of other phosphatases cannot be extrapolated to this nucleic acid of the instant invention for which no activity was demonstrated at the time of filing. Addition of a novel nucleic acid, while being a contribution over the prior art, is not substantial in terms of meeting patentable utility. The instant invention requires further research to reveal its activity and real-world use, which, as set forth in the utility guidelines referenced above, fails to meet the standards of patentable utility.

Finally, Applicant argues that the disclosure of the activity of the nucleic acid is not required by case law or statute and the commercial value of the instant invention should be sufficient to satisfy the utility requirement.

In response, without knowing the activity of a nucleic acid, its usefulness cannot be determined. Furthermore, the commercial value of the claimed invention has not been demonstrated.

Enablement

Claims 4,8,9 and 25-30 remain rejected under 35 U.S.C. 112, first paragraph. Specifically, since the claimed invention is not supported by either a specific and substantial asserted utility or a well established utility for the reasons set forth above, one skilled in the art clearly would not know how to use the claimed invention.

Claim 9 remains rejected for further grounds of enablement as set forth at pages 7-9 of the office action mailed 03/24/2004. Applicant has failed to respond to this ground of rejection and it is therefore maintained for reason of record.

Conclusion

THIS ACTION IS MADE FINAL.

Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Valarie Bertoglio whose telephone number is (571) 272-0725. The examiner can normally be reached on Mon-Thurs 5:30-4:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Ram Shukla can be reached on (571) 272-0735. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

Valarie Bertoglio
Examiner
Art Unit 1632

Scott D. Priebe

SCOTT D. PRIEBE, PH.D
PRIMARY EXAMINER